EXHIBIT 7

CONNETICS CORP

3400 W BAYSHORE RD PALO ALTO, CA 94303 415. 843.2800

10-K/A

AMENDMENT TO FORM 10-K Filed on 07/25/2006 - Period: 12/31/2005File Number 000-27406



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10–K/A

Amendment No. 1

 \square ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE **ACT OF 1934**

For the Transition Period from

Commission File Number: 0-27406

CONNETICS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization) 3160 Porter Drive, Palo Alto, California

94-3173928 (I.R.S. Employer Identification No.) 94304 (Zip Code)

(Address of principal executive offices)

Registrant's telephone number, including area code: (650) 843-2800

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, \$0.001 par value per share Preferred Share Purchase Rights

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🔲 No 💆 Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes □ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☑

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K/A or any amendment to this Annual Report on Form 10-K/A.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐ Accelerated Filer ☑ Non-Accelerated Filer ☐ Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

2004 and began selling the product in December 2004 in 50g and 100g trade unit sizes. Net product revenues for Evoclin Foam were \$24.8 million in 2005 and \$2.8 million for the fourth quarter of 2004. Evoclin Foam is contraindicated in individuals with a history of hypersensitivity to preparations containing clindamycin or lincomycin, a history of regional enteritis or ulcerative colitis, or a history of antibiotic—associated colitis.

PRODUCT CANDIDATES AND CLINICAL TRIALS

Our product candidates must go through extensive clinical evaluation and clearance by the FDA before we can sell them commercially. Our development model anticipates that we will conduct simultaneous studies on several products at a given time; however, we regularly re-evaluate our product development efforts. On the basis of these re-evaluations, we have in the past, and may in the future, abandon development efforts for particular products. Not all products or technologies under development will result in the successful introduction of a new product.

Desilux Foam

In September 2004, we commenced the Phase III clinical program for Desilux Foam, a low-potency topical steroid, formulated with 0.05% desonide in our proprietary emollient foam delivery vehicle. Desilux Foam is the first drug candidate for which we are seeking a pediatric label. The Phase III clinical program focused on atopic dermatitis, and on August 15, 2005, we announced the positive outcome of the clinical trial. The data from the trial demonstrate a consistently robust and highly statistically significant treatment effect for Desilux Foam compared to placebo foam on the primary trial composite endpoint evaluating improvement in the Investigator's Static Global Assessment, or ISGA, erythema and induration/papulation. The data from the trial also demonstrated that Desilux Foam was safe and well tolerated, with the most frequently observed side effects mild in nature and largely limited to application site reactions

In November 2005, we submitted an NDA for Desilux Foam to the FDA. In January 2006, the FDA accepted the NDA for filing with a user fee goal date of September 21, 2006. We anticipate receiving FDA approval of Desilux Foam in September 2006.

Primolux Foam

In March and April, 2005, we commenced Phase III clinical trials to evaluate Primolux Foam, a super high-potency topical steroid, formulated with 0.05% clobetasol propionate in our proprietary emollient foam delivery vehicle, VersaFoam-EF(TM). The Primolux Foam clinical program consisted of two Phase III trials, one focusing on psoriasis and the other on atopic dermatitis. The psoriasis trial was completed with positive results in September 2005 and the atopic dermatitis trial was completed with positive results in November 2005. In both psoriasis and atopic dermatitis, Primolux Foam demonstrated significant positive results for all endpoints. We plan to submit an NDA to the FDA for Primolux Foam in the first quarter of 2006.

Extina Foam

In April 2003, we announced summary results from our Phase III clinical trial with Extina Foam, a foam formulation of a 2% concentration of the antifungal drug ketoconazole for the treatment of seborrheic dermatitis. Ketoconazole is used to treat a variety of fungal infections, including seborrheic dermatitis, a chronic, recurrent skin condition. Industry sources estimate that seborrheic dermatitis affects 3–5% of the U.S. population. It usually involves the scalp, but also can affect the skin on other parts of

the body, including the face and chest. The symptoms of seborrheic dermatitis include itching, redness and scaling. In 2005 an estimated 1.1 million patients sought physician treatment for seborrheic dermatitis. Extina Foam is intended to compete primarily in the topical antifungal market, which industry sources estimate represented approximately \$735 million in U.S. prescriptions in 2005.

The Extina Foam clinical program consisted of a pivotal trial and two smaller supplemental clinical studies required by the FDA. As designed, the trial results demonstrated that Extina Foam was not inferior to Nizoral(R) (ketoconazole) 2% cream as measured by the primary endpoint of ISGA. The trial was also designed to compare Extina Foam to placebo foam per the ISGA. The result, although in favor of Extina Foam, did not achieve statistical significance. On all other endpoints, statistical significance was achieved; therefore, based on our belief that the totality of the data demonstrated that Extina Foam was clinically superior to placebo foam, we submitted an NDA to the FDA in July 2003.

In November 2004, the FDA issued a non-approvable letter for Extina Foam based on its conclusion that, although Extina Foam demonstrated

In November 2004, the FDA issued a non-approvable letter for Extina Foam based on its conclusion that, although Extina Foam demonstrated non-inferiority to the comparator drug currently on the market, it did not demonstrate statistically significant superiority to placebo foam. Following continued discussions with the FDA, we recommenced development of Extina Foam by initiating a Phase III trial in September 2005 intended to demonstrate that Extina Foam is superior to placebo foam. Pending positive results from this Phase III trial, we expect to submit a Class 2 Resubmission for Extina Foam to the FDA by the end of 2006.

Velac Gel

In December 2002, we initiated a Phase III program for Velac Gel, a combination of 1% clindamycin and 0.025% tretinoin, for the treatment of acne. The Velac Gel clinical program consisted of two pivotal trials designed to demonstrate superiority to the individual drug products, and two smaller supplemental clinical studies required by the FDA. We completed enrollment of both pivotal trials in late 2003, enrolling over 2,200 patients, and announced in March 2004 the positive outcome of the Phase III clinical trials. The data from each trial demonstrated a statistically superior treatment effect for Velac Gel compared with clindamycin gel, tretinoin gel and placebo gel on both of the primary endpoints. An analysis of the combined data from the clinical trials demonstrated similar results to the individual trials. The data from these trials also demonstrated that Velac Gel was safe and well tolerated, with the most commonly observed adverse effects being application site reactions such as burning, dryness, redness and peeling.

We submitted an NDA to the FDA for Velac Gel in August 2004. The FDA accepted the NDA for filing in October 2004 with a user fee goal date of June 25, 2005. On June 10, 2005, the FDA issued a non-approvable letter for Velac Gel, citing that "a positive carcinogenicity signal was detected in a Tg.AC mouse dermal carcinogenicity study." Nothing in our clinical trials indicated that the mouse study was predictive of human results. We have been actively engaged in discussions with the FDA about the additional steps required to obtain approval of Velac Gel, and we continue to perform development work related to the program.

Other Pipeline Formulations

In addition to the product candidates described above, we are developing foam technology for other disease indications. As part of our development model, we strive to have four product candidates in product formulation at any given time, so we have the flexibility in determining which two to move into human clinical trials. Our most promising preclinical candidates include an emulsion foam formulation of calcipotriene, a vitamin—D analog, for treatment of psoriasis; an aqueous foam formulation for the

combination of clindamycin and benzoyl peroxide in acne; and a topical formulation of acitretin (the active ingredient in Soriatane) for psoriasis. We are also exploring various product formulations for Liquipatch, which is described in more detail below under "Royalty-Bearing Products and Licensed

ROYALTY-BEARING PRODUCTS AND LICENSED TECHNOLOGY

Foam Technology. We are a party to a license agreement with Pfizer, Inc. (formerly Pharmacia Corporation) pursuant to which we granted Pfizer exclusive global rights, excluding Japan, to our proprietary foam drug delivery technology for use with Pfizer's Rogaine hair loss treatment. The license with Pfizer will expand the reach of the foam vehicle to the non-prescription (over-the-counter) pharmaceutical market. Under the agreement, Pfizer paid us an initial licensing fee, and agreed to pay us additional fees when it achieves specified milestones, plus a royalty on product sales. We recognized \$1.0 million under the agreement during 2002 related to license fees and milestone payments. During 2003, 2004 and 2005, we recognized \$86,000, \$11,000 and \$8,000, respectively, in license fees related to development costs. Pfizer is responsible for most product development activities and costs. Unless terminated earlier, the agreement with Pfizer will terminate on the first date on which all of Pfizer's obligations to pay royalties have expired or been terminated. In general, in each country (excluding Japan) where the manufacture, importation, distribution, marketing, sale or use of the product would infringe any of our issued patents covered by the agreement, Pfizer's obligation to pay patent royalties with respect to that country will expire automatically when the last of our patents to expire (or to be revoked) in that country actually expires (or is expired). One U.S. patent has been issued covering the minoxidil foam technology, and we have additional applications pending in this field. In January 2006, Pfizer received approval from the FDA to sell its Rogaine hair loss treatment using our proprietary foam drug delivery technology in the U.S., and is obligated to pay us royalties on future product sales.

We are a party to a number of other agreements relating to foam technology. We have licensed the technology of betamethasone valerate foam to Calltech licensed the worldwide rights to their patent on the steroid foam technology, to us In 2003, we howfit the rights to the

Celltech plc in Europe, and Celltech licensed the worldwide rights to their patent on the steroid foam technology to us. In 2003, we bought the rights to the U.S. patent from Celltech. In May 2004, Celltech was acquired by UCB Pharma, or UCB, a subsidiary of UCB Group. We pay UCB royalties on all sales worldwide of foam formulations containing steroids. UCB markets its product as Bettamousse(R) (the product equivalent of Luxíq), and UCB paid us royalties for its sales under the betamethasone valerate foam license through April 2003, at which time its royalty obligation under the contract ceased. We have license agreements with Bayer (in the U.S.) and Pfizer and Mipharm (internationally) for the use of pyrethrin foam for head lice. The head lice product is marketed as RID(R) in the U.S., as Banlice(R) in Australia, and as Milice(R) in Italy. We receive royalties on sales of those products. In February 2004, we entered into an agreement to license ketoconazole foam to Mipharm in exchange for an initial fee of \$90,000, plus future milestone and royalty payments. In 2004 and 2005, on a consolidated basis, we received \$244,000 and \$359,000, respectively, in royalties for foam-based technology.

As discussed above under "OLUX and Luxíq Foams," we licensed the commercial rights to Mipharm to market and sell OLUX Foam in Italy and the

U.K., and we will receive milestone payments and royalties on future product sales. We have received \$309,000 under the agreement through December 31, 2005. Based on the minimum royalty provisions in the agreement and assuming the agreement stays in force through 2021, the aggregate potential minimum royalties under the contract are \$975,000. Unless terminated earlier, the agreement with Mipharm will terminate on the later of September 2021 and the last expiration date of the patents covering the aerosol mousse technology, which is currently 2015. We have also granted exclusive commercial rights to Pierre Fabre to market and sell OLUX Foam in Europe, excluding Italy and the U.K., and certain countries in South America and Africa.

Genentech, Inc., and Amevive(TM), marketed by Biogen/ IDEC. Evoclin Foam competes primarily in the topical antibiotic acne market. Competition in this market includes generic and branded clindamycin and erythromycin, including branded products Clindagel marketed by Galderma S.A., Cleocin-T marketed by Pfizer, Inc., and Clindets marketed by Stiefel Laboratories, Inc. Generic and branded combinations of clindamycin and benzoyl peroxide, such as Benzaclin marketed by Dermik and Duac marketed by Stiefel, and erythromycin and benzoyl peroxide, such as Benzamycin marketed by Dermik, also present competition for Evoclin Foam.

Many of our existing or potential competitors, particularly large pharmaceutical companies, have substantially greater financial, marketing, sales, technical and human resources than we do. Furthermore, many of our competitors are private companies or divisions of much larger companies that do not have the same disclosure obligations regarding their product development and marketing strategies and plans that we do as a public company, which puts us at a distinct competitive disadvantage relative to these competitors. Our products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions addressed by our products, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our competitors.

CUSTOMERS

We sell our products directly to distributors, who in turn sell the products into the retail marketplace. Our customers include the nation's leading wholesale pharmaceutical distributors, such as Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Corporation. Walgreens, a national retail pharmacy chain, was also one of our customers until January 2006 when it began purchasing our products directly from a distributor. We entered into a distribution agreement with each of Cardinal Health, Inc. and McKesson Corporation in December 2004 and with AmerisourceBergen in September 2005 under which we agreed to pay a fee to each of these distributors in exchange for certain product distribution, inventory information, return goods processing, and administrative services. While these agreements provide us with inventory level reports from these distributors, we must also rely on historical prescription information to estimate future demand for our products and to estimate the amount of reserves for rebates, chargebacks, and returns. During 2005, McKesson, Cardinal, and AmerisourceBergen accounted for 36%, 34%, and 11%, respectively, of our net product revenues. RESEARCH AND DEVELOPMENT AND PRODUCT PIPELINE

Innovation by our research and development operations contributes to the success of our business. Our research and development expenses were

Innovation by our research and development operations contributes to the success of our business. Our research and development expenses were \$31.9 million in 2005, \$21.5 million in 2004, and \$30.1 million in 2003. Our goal is to develop and bring to market innovative products that address unmet healthcare needs. Our substantial investment in research and development and our active in-licensing strategy both support this goal.

Our development activities involve work related to product formulation, preclinical and clinical study coordination, regulatory administration, manufacturing, and quality control and assurance. Unlike many pharmaceutical companies that conduct early stage research and drug discovery, we focus on later—stage development. We believe this approach helps to minimize the risk and time requirements for us to get a product on the market. Our strategy involves targeting product candidates we believe have attractive market potential, and then rapidly evaluating and formulating new therapeutics by using previously approved active ingredients reformulated in our proprietary delivery system. This product development strategy allows us to conduct limited preclinical safety trials, and to move rapidly into safety and efficacy testing in humans with products that offer significant improvements over existing products. A secondary strategy we pursue is to evaluate the acquisition of products from other companies.

GOVERNMENT REGULATION

Generally — Product Development. The pharmaceutical industry is subject to regulation by the FDA under the Food, Drug and Cosmetic Act, by the states under state food and drug laws, and by similar agencies outside of the United States. In order to clinically test, manufacture, and market products for therapeutic use, we must satisfy mandatory procedures and safety and effectiveness standards established by various regulatory bodies. A more detailed explanation of the standards we are subject to is provided under "Risk Factors — We may spend a significant amount of money to obtain FDA and other regulatory approvals, which may never be granted" and "— We cannot sell our current products and product candidates if we do not obtain and maintain governmental approvals" below.

All of our prescription pharmaceutical products will require regulatory approval by governmental agencies before they can be commercialized. The nature and extent of the review process for our potential products will vary depending on the regulatory categorization of particular products. Federal, state, and international regulatory bodies govern or influence, among other things, the testing, manufacture, labeling, storage, record keeping, approval, advertising, and promotion of our products on a product-by-product basis. Failure to comply with applicable requirements can result in warning letters, fines, injunctions, penalties, recall or seizure of products, total or partial suspension of production, denial or withdrawal of approval, and civil or criminal prosecution. Accordingly, initial and ongoing regulation by governmental entities in the U.S. and other countries is a significant factor in the production and marketing of any pharmaceutical products that we have or may develop.

Product development and approval within this regulatory framework, and the subsequent compliance with appropriate federal and foreign statutes and

Product development and approval within this regulatory framework, and the subsequent compliance with appropriate federal and foreign statutes and regulations, takes a number of years and involves the expenditure of substantial resources.

FDA Approval. The general process for approval by the FDA is as follows:

- Preclinical Testing. Generally, a company must conduct preclinical studies before it can obtain FDA approval for a new therapeutic agent. The basic purpose of preclinical investigation is to gather enough evidence on a potential new agent through laboratory and animal testing to demonstrate there is a reasonable enough expectation of efficacy to justify exposing humans to the risk of adverse events associated with any new drug, and to demonstrate there are no safety signals that would suggest it would not be prudent to begin preliminary trials in humans. The sponsor of these studies submits the results to the FDA as a part of an investigational new drug application, or IND, that the FDA must review before human clinical trials of an investigational drug can start. FDA approval of new drug candidates requires an adequate demonstration of safety and efficacy in man. For each investigational product entering clinical trials, we are required to file an IND and perform our clinical studies to IND standards set by the FDA.
- Clinical Trials. Clinical trials are normally done in three distinct phases and generally take two to five years, but may take longer, to complete:
 Phase I trials generally involve administration of a product to a small number of patients to determine safety, tolerance and the metabolic and pharmacologic actions of the agent in humans and the side effects associated with increasing doses.
 - Phase II trials generally involve administration of a product to a larger group of patients with a particular disease to obtain evidence of the agent's
 effectiveness against the targeted disease, to further explore risk and side effect issues, and to confirm preliminary

data regarding optimal dosage ranges.

Phase III trials involve more patients, and often more locations and clinical investigators than the earlier trials. At least one such trial is required for

FDA approval to market a branded, or non-generic, drug.

The rate of completion of our clinical trials depends upon, among other factors, the rate at which patients enroll in the study. Patient enrollment is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the study, and the sometimes seasonal nature of certain dermatological conditions. Delays in planned patient enrollment may result in increased costs and delays, which could have a material adverse effect on our business. In addition, side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval.

Regulatory Submissions. The Food, Drug and Cosmetic Act outlines the process by which a company can request approval to commercialize a new product. After we complete the clinical trials of a new drug product, we must file an NDA with the FDA. We used the so-called 505(b)(2) application process for OLUX, Luxíq, and Evoclin, which permitted us in each case to satisfy the requirements for a full NDA by relying on published studies or the FDA's findings of safety and effectiveness based on studies in a previously-approved NDA sponsored by another applicant, together with the studies generated on our products. If studies previously submitted by another applicant and relied upon as part of 505(b)(2) application are found by the FDA not to be up to contemporary standards, it may be necessary to repeat them. The FDA may also require 505(b)(2) applicants to provide additional safety data that was not required at the time of the original application. Generally, however, the number of clinical trials required to support a 505(b)(2) application, and the amount of information in the application itself, may be substantially less than that required to support a traditional NDA application. The 505(b)(2) process will not be available for all of our other product candidates, and as a result the drug development process may be longer for our future product candidates than it has been for our products to date. The FDA may also require an applicant to conduct post-approval studies or implement risk management programs that do not delay market entry but do increase product-related research and development costs.

We must receive FDA clearance before we can commercialize any product, and the FDA may not grant approval on a timely basis or at all. The FDA can take between one and two years to review an NDA, and can take longer if significant questions arise during the review process. In addition, if there are changes in FDA policy while we are in product development, we may encounter delays or rejections that we did not anticipate when we submitted the NDA for that product. We may not obtain regulatory approval for any products that we develop, even after committing such time and expenditures to the process. Even if regulatory approval of a product is granted, it may entail limitations on the indicated uses for which the product may be marketed.

Manufacturing. The FDA regulates and inspects equipment, facilities, and processes used to manufacture pharmaceutical products before providing approval to market a product. If we make a material change in manufacturing equipment, location, or process, we may have to undergo additional regulatory review. We and our contract manufacturers must adhere to GMP and product-specific regulations enforced by the FDA. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes after the initial approval. If the FDA determines that our (or our contract manufacturers' equipment, facilities, or processes do not comply with applicable FDA regulations and conditions for product approval, the FDA may seek sanctions and/or remedies against us, including suspension of our manufacturing operations.

products. This in turn could cause a loss of our market share and negatively affect our revenues. Numerous factors could cause interruptions in the supply of our finished products, including shortages in raw material required by our manufacturers, changes in our sources for manufacturing, our failure to timely locate and obtain replacement manufacturers as needed, and conditions affecting the cost and availability of raw materials.

Orders for our products may decrease depending on the inventory levels held by our major customers. Significant changes in orders from our major

customers could cause our operating results to vary significantly from quarter to quarter.

Retail availability of our products is greatly affected by the inventory levels our customers hold. We monitor wholesaler inventory of our products using a combination of methods, including information provided by the customers as well as tracking prescriptions filled at the pharmacy level to determine amounts the wholesalers have sold to their customers. Pursuant to our distribution service agreements with Cardinal, McKesson and AmerisourceBergen, we receive inventory level reports, but until December 2005 the reports we received contained inaccuracies and inconsistencies that made them unreliable. Based on reporting in December 2005, we concluded that our product inventory at those wholesalers was higher than previously estimated. For other wholesalers that do not provide us with inventory level reports, our estimates may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels or reporting inaccuracies from the wholesalers may result in excessive inventory production, excess product available at the retail level, and unexpected increases or decreases in orders from our major customers. These changes may cause our net revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or projections. If our financial results are below expectations for a particular period, the market price of our securities may drop significantly. See also "Risk Factors Related to Our Business — Our decision to reduce wholesale inventory could decrease our product revenue."

We cannot sell our current products and product candidates if we do not obtain and maintain governmental approvals.

Pharmaceutical companies are subject to heavy regulation by a number of national, state and local agencies. Of particular importance is the FDA. The FDA has jurisdiction over all of our business and administers requirements covering testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. If we fail to comply with applicable regulatory requirements, we could be subject to fines, suspensions of regulatory approvals of products, product recalls, delays in product distribution, marketing and sale, and civil or criminal sanctions.

The process of obtaining and maintaining regulatory approvals to

The process of obtaining and maintaining regulatory approvals for pharmaceutical products, and obtaining and maintaining regulatory approvals to market these products for new indications, is lengthy, expensive and uncertain. The manufacturing and marketing of drugs, including our products, are subject to continuing FDA and foreign regulatory review, and later discovery of previously unknown problems with a product, manufacturing process or facility may result in restrictions, including recall or withdrawal of the product from the market. The FDA is permitted to revisit and change its prior determinations and it may change its position with regard to the safety or effectiveness of our products. Even before any formal regulatory action, we could voluntarily decide to cease distribution and sale or recall any of our products if concerns about safety or effectiveness develop.

In its regulation of advertising, the FDA from time to time issues correspondence to pharmaceutical companies alleging that some advertising or promotional practices are false, misleading or

deceptive. The FDA has the power to impose a wide array of sanctions on companies for such advertising practices, and if we were to receive correspondence from the FDA alleging these practices we might be required to:

- change our methods of marketing and selling products,
- take FDA-mandated corrective action, which could include placing advertisements or sending letters to physicians rescinding previous advertisements or promotion.
- · incur substantial expenses, including fines, penalties, legal fees and costs to comply with the FDA's requirements,
- disrupt the distribution of products and stop sales until we are in compliance with the FDA's position.

We may spend a significant amount of money to obtain FDA and other regulatory approvals, which may never be granted. Failure to obtain such regulatory

approvals could adversely affect our prospects for future revenue growth.

Successful product development in our industry is highly uncertain, and the process of obtaining FDA and other regulatory approvals is lengthy and expensive. Very few research and development projects produce a commercial product. Product candidates that appear promising in the early phases of development may fail to reach the market for a number of reasons, including that the product candidate did not demonstrate acceptable clinical trial results in humans even though it demonstrated positive preclinical trial results, or that the product candidate was not effective in treating a specified condition or illness. The FDA may also require additional clinical data to support approval. The FDA can take between one and two years to review new drug applications, or longer if significant questions arise during the review process. Moreover, the costs to obtain approvals could be considerable and the failure to obtain, or delays in obtaining, an approval could have a significant negative effect on our business. For example, in November 2004, the FDA notified us that it would not approve our NDA for Extina Foam based on its conclusion that, although Extina Foam demonstrated non-inferiority to the comparator drug currently on the market, it did not demonstrate statistically significant superiority to placebo foam. In addition, on June 10, 2005, the FDA issued a non-approvable letter for Velac Gel, citing that "a positive carcinogenicity signal was detected in a Tg. AC mouse dermal carcinogenicity study."

We depend on a limited number of customers, and if we lose any of them, our business could be harmed.

Our customers include the nation's leading wholesale pharmaceutical distributors, such as Cardinal Health, Inc., McKesson, Corporation, and AmerisourceBergen Corporation. During 2005, McKesson, Cardinal, AmerisourceBergen accounted for 36%, 34%, and 11%, respectively, of our net product revenues. The distribution network for pharmaceutical products is subject to increasing consolidation, and a few large wholesale distributors control a significant share of the market. In addition, the number of independent drug stores and small chains has decreased as retail consolidation has occurred. Further consolidation among, or any financial difficulties of, distributors or retailers could result in the combination or elimination of warehouses, which may result in reductions in purchases of our products, returns of our products, or cause a reduction in the inventory levels of distributors and retailers, any of which could have a material adverse impact on our business. If we lose any of these customer accounts, or if our relationship with them were to deteriorate,

our business could also be materially and adversely affected.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our Consolidated Financial Statements and related Notes to Consolidated Financial Statements contained elsewhere in filed with this Annual Report on Form 10–K/A. Except as discussed above, we have not modified or updated disclosures presented in the original Annual Report on Form 10–K, filed on March 13, 2006, other than as required to reflect the effects of the restatement. As such, this Annual Report on Form 10–K/A does not reflect events that occurred after we filed our original Annual Report on Form 10–K and does not modify or update those disclosures affected by subsequent events, except as specifically referenced in the disclosures. We have made no changes to information not affected by the restatement, and therefore we have omitted all such unchanged information that reflects the disclosures made at the time of the original filing of the Annual Report on Form 10–K.

As announced in our Current Report on Form 8–K filed on May 3, 2006, after we filed our Original 10–K, we concluded that our previously filed consolidated financial statements should no longer be relied upon due to errors in the accounting for accruals for estimated rebates and chargebacks for our products. Because we were already examining revenue reserves in prior years, management decided to apply the same resources to evaluate how we estimate accruals for returns of our products. As a result of our evaluation, we determined that our methodology for estimating future product returns had contained errors and resulted in an understatement of our returns accruals. We also recorded certain other immaterial adjustments associated with the revenue reserve adjustments. Note 2 of Notes to the Consolidated Financial Statements details the adjustments made to historical data as of December 31, 2005 and 2004 and for each of the three years in the period ended December 31, 2005.

Rebates are contractual discounts offered to government programs and private health plans that are eligible for such discounts at the time prescriptions are dispensed, subject to various conditions. Chargebacks represent discounts that our wholesale customers charge us for the difference between the then—current retail price and the lower price they are paid by certain government entities who are entitled to discounts under contracts with us. We record provisions for rebates and chargebacks by estimating these liabilities as products are sold, based on factors such as timing and terms of plans under contract, time to process rebates, product pricing, sales volumes, amount of inventory in the distribution channel, and prescription trends. As part of our procedures to prepare for the closing of the first quarter of 2006 financial statements, during March and April 2006, we revised our accounting process for estimating revenue—related reserves, including rebates and chargebacks. As part of this process, we determined that our rebate and chargeback accruals had not been adequately capturing the full liability associated with the amount of product inventory in the distribution channel. We concluded that the impact of the revised methodology required us to restate our financial statements.

Our revised rebate and chargeback methodology is intended to fully capture our liability for (1) incurred—but—uninvoiced rebates and unprocessed chargebacks, and (2) future rebate and chargebacks associated with product inventory held in the distribution channel at period end, as required by U.S. generally accepted accounting principles. Our revised methodology also addresses factors such as anticipated price increases on our products and estimated future usage of our products by Medicaid programs and managed care organizations.

We have also determined that our prior methodology for estimating future product returns contained

errors and resulted in an understatement of our returns accrual. Previously, we estimated the return rate based on our cumulative historical return experience with related units shipped since initial sale and other relevant qualitative factors. For two of our products, OLUX and Luxíq, we applied the estimated return rate to the units in the distribution channel at period end, which was a smaller population than all units with potential risk of return. For our other two products, Soriatane and Evoclin, we calculated the value of the estimated units to be returned using the original sales price without taking into account price increases which were implemented between the date of sale through the period of the accrual. We permit wholesalers to return expired or expiring product for a credit at the then-current sales price less 5%, so the initial sales price may not fully capture our liability for future returns. As a result of our evaluation, we determined that our accruals for product returns had been understated. Our revised methodology estimates the return rate on the most recent three years' data, resulting in an estimated rate that is more responsive to current return trends. We assess the risk of return on a production lot basis and apply our estimated return rate to the units at risk for return. Immaterial Adjustments

In addition, because we have restated for these items, we have recorded certain immaterial adjustments as of December 31, 2005 and 2004 and for each of the three years in the period ended December 31, 2005.

Impact of Restatement

As a result of our analysis of rebate and chargeback accruals and accruals for returns of our products, we have restated our consolidated financial statements for each of the five years in the period ended December 31, 2005 The increased accrual for estimated rebates and chargebacks had the cumulative effect of decreasing net product revenues by \$7.4 million through December 31, 2005; the increased accrual for estimated returns had the cumulative effect of decreasing net product revenues by \$3.7 million through December 31, 2005. The table below sets forth the income statement impact of the increased accrual for estimated rebates and chargebacks and accruals for product returns for each of the five years in the period ended December 31, 2005 (in thousands):

	Reb	ates and			
Year ended December 31,	<u>Cha</u>	rgebacks	Re	eturns_	Total
2001	\$	250	\$	363	\$ 613
		431		847	1,278
2002. 2003		(431)		598	167
2004		221	000000000000000000000000000000000000000	916 931	1,137
2005		6,964		931	7,895
m . 4	•	= 40 =		2 /==	A 11 000
Total	\$	7,435	\$	3,655	\$ 11,090
44					

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Connetics Corporation a Delaware corporation

By:

/s/ John L. Higgins

John L. Higgins Chief Financial Officer Executive Vice President, Finance and Corporate Development

Date: July 24, 2006

74

The tables below set forth the effect of the adjustments for the four quarters in the year ended December 31, 2005:

	Three Mo	onths Ended March 3	1, 2005	Three Months Ended June 30, 2005					
		(unaudited)		(unaudited)					
	As Previously Reported	Revenue Reserve <u>Adjustments</u> (a)	As <u>Restated</u>	As Previously <u>Reported</u>	Revenue Reserve <u>Adjustments</u> (b)	As <u>Restated</u>			
Net product revenues: Soriatane OLUX Foam Evoclin Foam Luxíq Foam Other	\$ 17,581 15,792 3,067 5,654 96	\$ (1,217) (808) (27) —	\$ 16,364 14,984 3,040 5,721 96	\$ 18,334 14,033 7,037 5,835	\$ (591) 380 (79) -	\$ 17,743 14,413 6,958 6,224			
Total net product revenues Royalty and contract revenues	42,190 181	(1,985) —	40,205 181	45,239 130	99 —	45,338 130			
Total net revenues Operating costs and expenses	42,371 40,872	(1,985)	40,386 40,872	45,369 42,695	99	45,468 42,695			
Income (loss) from operations Interest and other income (expense), net	1,499 (353)	(1,985)	(486) (353)	2,674 (19)	99 —	2,773 (19)			
Income (loss) before income taxes Income tax provision (benefit)	1,146 105	(1 ,985) —	(839) 105	2,655 153	99 —	2,754 153			
Net income (loss)	\$ 1,041	\$ (1,985)	\$ (944)	\$ 2,502	\$ 99	\$ 2,601			
Net income (loss) per share: Basic	\$ 0.03		\$ (0.03)	\$ 0.07		\$ 0.07			
Diluted	\$ 0.03		\$ (0.03)	\$ 0.07		\$ 0.07			
Shares used to compute basic and diluted net income (loss) per share:	25 (00		35,699	34.825		34,825			
Basic Diluted	35,699 38,014		35,699	37,093	inceptation of the	37,093			
(a)			2005 in		ment for the period encrebate and chargeback				
(b)			2005 in	cludes a decrease of ents partially offset	ment for the period en \$200,000 for rebate ar by an increase of \$101	d chargeback			

	Thr	ee Months Ended S	September 30, 2	Three Months Ended December 31, 2005					
		(unaudi	ted)		(unaudited)				
	As Previously Reported	Revenue Reserve <u>Adjustments</u> (a)	As <u>Restated</u>	As Previously Reported	Revenue Reserve <u>Adjustments</u> (b)	Other Adjustments	As <u>Restated</u>		
Net product revenues:				KAMBATURI TATU MENGENERA MENGENERA DI BANGGUNAS		(c)			
Soriatane OLUX Foam	\$ 23,077 17,323	\$ (2,273) (1,444)	\$ 20,804 15,879	\$ 13,603 14,646	\$ 1,350 (1,913)	\$	\$ 14,953 12,733		
Evoclin Foam	7,724	(205)	7,519	6,851	415		7,266		
Luxíq Foam Other	7,014 45	(473) —	6,541 45	5,599 1	(1,466) —	######################################	4,133 1		
Total net product revenues	55,183	(4,395)	50,788	40,700	(1,614)		39,086		
Royalty and contract revenues	158	_	158	483	_	_	483		
Total net	EE 241	(4.20E)	E0.044	41 102	(1.614)		20.560		
revenues Operating costs and	55,341	(4,395)	50,946	41,183	(1,614)	 -	39,569		
expenses	39,666	_	39,666	37,134	_	4	37,138		
Income (loss) from operations Interest and other	15,675	(4,395)	11,280	4,049	(1,614)	(4)	2,431		
income (expense), net	160	_	160	413	_	_	413		
Income (loss) before income taxes	15,835	(4,395)	11,440	4,462	(1,614)	(4)	2,844		
Income tax provision (benefit)	470	_	470	(10,588)	_	(62)	(10,650)		
Net income (loss)	\$ 15,365	\$ (4,395)	\$ 10,970	\$ 15,050	\$ (1,614)	\$ 58	\$ 13,494		
Net income (loss) per share:			4X X 2000				A-0000400-110000000000000000000000000000		
Basic	\$ 0.44		\$ 0.31	\$ 0.44			\$ 0.39		
Diluted	\$ 0.39		\$ 0.29	\$ 0.40			\$ 0.36		
Shares used to compute basic and diluted net income (loss) per share:									
Basic Diluted	35,075 40,812		35,075 40,812	34,570 39,735			34,570 39,735		
(a)				Septem	enue reserves adjustments and spack adjustments and spack adjustments and space and space and space adjustments and space adjustments adjustments and space adjustments adjust	\$3.9 million for reba			
(b)				Deceml chargeb	enue reserves adjustn ber 31, 2005 includes back adjustments, part 00 for returns.	\$2.6 million for rebar	te and		
(c)					tax provision (benefit		f \$62,000		

Income tax provision (benefit) – The adjustment of \$62,000 represents the tax effect of the adjustments.

The table below sets forth the effect of the adjustments on the balance sheet as of December 31, 2004:

	December 31, 2004							
	As Previously Reported	Revenue Reserve <u>Adjustments</u>	Other <u>Adjustments</u>	As Restated				
Accounts receivable, net of cash discounts and allowances of \$708 (a) Other current assets Long-term assets	\$ 28,191 87,927 147,159	70 \$	\$ = 20	\$ 28,191 87,947 147,159				
Total assets	263,277	_	20	263,297				
Product-related accruals (a) (b) (c) Other current liabilities (c) Long-term liabilities	18,426 26,511 90,420	3,195	(1 47)	21,621 26,364 90,420				
Total liabilities Accumulated deficit Other stockholders' equity	135,357 (111,173) 239,093	3,195 (3,195)	(147) 167 —	138,405 (114,201) 239,093				
Total stockholders' equity	127,920	(3,195)	167	124,892				

Total liabilities and stockholders' equity

263,277

\$

\$

20

\$ 263,297

\$ F-12

Filed 08/13/2007 Page 18 of 21 Case 3:07-cv-02940-SI Document 23-4

Table of Contents

(b)

(c)

Accruals for product returns and chargebacks were previously netted against accounts receivable and have been reclassified to (a) product-related accruals.

> Product-related accruals — the adjustment of \$3.2 million represents \$471,000 million related to an increase in our rebates and chargebacks reserves and \$2.7 million related to an increase in our returns reserve.

Accruals for payments due to wholesalers under distribution service agreements that were previously included as other accrued liabilities have been reclassified to product-related accruals.

The table below sets forth the effect of the adjustments on the Consolidated Statement of Operations for the year ended December 31, 2004:

			Year Ended December 31, 2004								
		Previously Reported	Revenue Reserve Adjustments		Oti Adjust	her tments	As Restated				
Net revenues: Product (a) Royalty and contract	\$	142,059 2,296	\$	(1,137)	\$		\$140,922 2,296				
Total net revenues Operating costs and expenses		144,355 122,372		(1,137)		(33)	143,218 122,339				
Income (loss) from operations Interest and other income (expense), net		21,983 (1,475)		(1,137)		33	20,879 (1,475)				
Income (loss) before income taxes Income tax provision (benefit) (b)		20,508 1,493		(1,137)		33 (24)	19,404 1,469				
Net income (loss)	\$	19,015	\$	(1,137)	\$	57	\$ 17,935				
Net income (loss) per share: Basic	\$	0.54					\$ 0.51				
Diluted	\$	0.51					\$ 0.48				
Shares used to compute basic and diluted net income (loss) per share: Basic		35,036					35,036				
Diluted		37,443					37,443				
(a)		repres relate	sents an ined to an inc	enues — Th crease in our crease in our d to an incre	r revenue re rebates and	eserves of \$ d chargebac	221,000 ks reserve and				
(b)		Incon repres	ne tax pro- sents the t	vision (benef ax effect of t	fit) – The a he adjustm	djustment o ents.	f \$24,000				
	F-13										

The tables below set forth the effect of the adjustments for the four quarters in the year ended December 31, 2004:

	Three Mont	ths Ended March 31 (unaudited)	, 2004	Three Months Ended June 30, 2004 (unaudited)					
	As Previously Reported	Revenue Reserve <u>Adjustments</u> (a)	As <u>Restated</u>	As Previously <u>Reported</u>	Revenue Reserve Adjustments (b)	As <u>Restated</u>			
Net product revenues: Soriatane OLUX Foam Luxíq Foam Other	\$ 3,640 14,370 5,471 85	\$ (8) (397) (18)	\$ 3,632 13,973 5,453 85	\$ 17,154 15,223 5,614 8	\$ (136) 86 447	\$ 17,018 15,309 6,061 8			
Total net product revenues Royalty and contract	23,566 1,416	(423)	23,143 1,416	37,999 254	39 7	38,396 254			
Total net revenues Operating costs and expenses	24,982 22,574	(423) —	24,559 22,574	38,253 29,541	397 —	38,650 29,541			
Income (loss) from operations Interest and other income (expense), net	2,408 (292)	(423) —	1,985 (292)	8,712 (608)	397 —	9,109			
Income (loss) before income taxes Income tax provision (benefit)	2,116 243	(423)	1,693 243	8,104 647	397.	8,501 647			
Net income (loss)	\$ 1,873	\$ (423)	\$ 1,450	\$ 7,457	\$ 397	\$ 7,854			
Net income (loss) per share: Basic	\$ 0.06		\$ 0.04	\$ 0.21		\$ 0.22			
Diluted	\$ 0.05		\$ 0.04	\$ 0.19		\$ 0.21			
Shares used to compute basic and diluted net income (loss) per share: Basic Diluted	33,587 35,887		33,587 35,887	35,242 41,627		35,242 41,627			
(a)			20		ljustment for the period end for rebate and chargeback s.				
(b)			20	04 includes \$249,000	ljustment for the period end for returns, offset by a \$6- nd chargeback liability.	ded June 30, 46,000			

	Three Mont	hs Ended September (unaudited)	r 30, 2004	Three Months Ended December 31, 2004 (unaudited)					
	Previously Reserve As Previously Reser <u>Reported Adjustments Restated Reported Adjustm</u>		Revenue Reserve <u>Adjustments</u> (b)	Other <u>Adjustments</u>	As <u>Restated</u>				
Net product revenues: Soriatane OLUX Foam Evoclin Foam Luxíq Foam Other	\$ 14,724 15,962 6,281 32	\$ 130 (250) ————————————————————————————————————	\$ 14,854 15,712 6,185 32	\$ 18,049 16,339 2,883 6,216 8	\$ (91) (600) (45) (159)		\$ 17,958 15,739 2,838 6,057 8		
Total net product revenues Royalty and contract revenues	36,999 345	(216)	36,783 345	43,495 281	(895)		42,600 281		
Total net revenues Operating costs and expenses	37,344 33,132	(216) —	37,128 33,132	43,776 37,125	(895)	(33)	42,881 37,092		
Income (loss) from operations Interest and other income (expense),	4,212	(216)	3,996	6,651	(895)	33	5,789		
net Income (loss) before income taxes Income tax provision (benefit)	(373) 		(373) 3,623 144	(202) 6,449 459	(895)	33 (24)	(202) 5,587 435		
Net income (loss)	3,695	\$ (216)	\$ 3,479	\$ 5,990	\$ (895)	\$ 57	\$ 5,152		
Net income (loss) per share: Basic	\$ 0.10		\$ 0.10	\$ 0.17			\$ 0.14		
Diluted	\$ 0.10		\$ 0.09	\$ 0.16			\$ 0.13		
Shares used to compute basic and diluted net income (loss) per share: Basic	35,510		35,510	35,695			35,695		
Diluted	38,064		38,064	38,172			38,172		

(a)

The revenue reserves adjustment for the period ended September 30, 2004 includes \$197,000 for rebate and chargebacks and \$19,000 for returns.

(b)

The revenue reserves adjustment for the period ended December 31, 2005 includes \$467,000 for rebate and chargeback adjustments and \$428,000 for returns.

The table below sets forth the effect of the adjustments on the Consolidated Statement of Operations for the year ended December 31, 2003:

	Year Ended December 31, 2003									
THE MET WHICH ALL SELECTION AND AN ADDRESS OF THE SECOND OF THE SECOND S	As Previously Reported		Revenue Reserve <u>Adjustments</u>		Other <u>Adjustments</u>		As <u>Restated</u>			
Net revenues: Product (a) Royalty and contract	\$	66,606 8,725	\$	(167)	\$		\$ 66,439 8,725			
Total net revenues Operating costs and expenses	S. S	75,331 77,838	Josef (1)	(167)		(76)	75,164 77,762			
Income (loss) from operations Interest and other income (expense), net		(2,507) (4 26)		(167)		76 —	(2,598) (426)			
Income (loss) before income taxes Income tax provision (benefit) (b)	ijas sijas sijas asas asas il	(2,933) 1,167		(167)		76 (34)	(3,024) 1,133			
Net income (loss)	\$	(4,100)	\$	(167)	\$	110	\$ (4,157)			

Net income (loss) per share:

Basic	\$ (0.13)	\$	(0.13)		
Diluted	\$ 10 miles (0.13)	\$	(0.13)		
share:	o compute basic and diluted net income (loss) per 31,559		31,559		
Diluted	31,559		31,559		
F-15					

Case 3:07-cv-02940-SI Document 23-4 Filed 08/13/2007 Page 21 of 21